

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

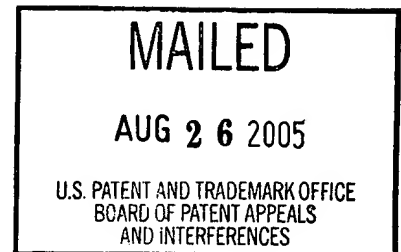
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LINDA G. CIMA,
EDWARD W. MERRILL, and PHILIP R. KUHL

Appeal No. 2005-0854
Application No. 08/398,555

ON BRIEF¹



Before SCHEINER, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 14-17 and 32-34, which are all the claims pending in the application.

Claims 14-17, 33, and 34 are illustrative of the subject matter on appeal and are reproduced below:

33. A method for growing eukaryotic cells comprising bringing into contact the cells with a composition comprising
a biocompatible solid substrate,
biocompatible polymeric tethers, and

¹ Appellants waived (Paper received May 16, 2005) their request for oral hearing. Accordingly, we considered this appeal on Brief.

growth effector molecules,

wherein one end of each tether is covalently linked to the substrate and one end is covalently linked to a growth effector molecule so that the growth effector molecule cannot be internalized by cells attached to the substrate;

wherein the growth effector molecules are attached to the substrate in a concentration effective to enhance the rate of target cell growth over the rate of target cell growth with soluble growth effector molecules and growth effector molecules adsorbed to a substrate, without internalization of the molecules; and

wherein the tether is covalently linked to the substrate and to the growth effector molecule by the same attachment agents, maintaining the cells in contact with the composition under conditions and for a time sufficient to cause the cells to grow.

14. The method of claim 33 wherein the attachment agent is selected from the group consisting of cyanogen bromide, succinimide, aldehyde, tosyl chloride, avidin-biotin, epoxide, maleimide, and carbodiimide.
15. The method of claim 14 wherein the composition is administered by injection, infusion, or implantation.
16. The method of claim 15 wherein the composition is administered by implantation of the composition and wherein the substrate is shaped to match a desired tissue shape.
17. The method of claim 16 wherein the substrate is biodegradable.
34. A method of testing a compound for an effect on tissue comprising bringing into contact the compound to be tested and a composition comprising
 - a biocompatible solid substrate,
 - biocompatible, polymeric tethers,
 - growth effector molecules, and
 - growing cells,wherein one end of each tether is covalently linked to the substrate and one end is covalently linked to a growth effector molecule so that the growth effector molecule cannot be internalized by cells attached to the substrate;
 - wherein the growth effector molecules are attached to the substrate in a concentration effective to enhance the rate of target cell growth over the rate of target cell growth with soluble growth effector molecules and growth effector molecules adsorbed to a substrate, without internalization of the molecules;

wherein the tether is covalently linked to the substrate and to the growth effector molecule by the same attachment agents; and

wherein the growing cells are bound to the growth effector molecules; incubating the compound and the composition under conditions promoting cell growth; and observing the cells for any effect not observed in cells not brought into contact with the composition.

The references relied upon by the examiner are:

Nitecki et al. (Nitecki)	4,954,637	Sep. 4, 1990
Merrill	5,171,264	Dec. 15, 1992
Herweck et al. (Herweck)	5,370,681	Dec. 6, 1994
Kausch et al. (Kausch)	5,508,164	Apr. 16, 1996
Mikos	5,522,895	Jun. 4, 1996
Cima et al. ('828)	5,906,828	May 25, 1999
Cima et al. ('818)	6,045,818	Apr. 4, 2000

GROUND OF REJECTION

Claims 14-17 and 33 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,906,828 in view of Nitecki, Kausch and appellants' admitted prior art at page 12, lines 1-12 of the specification.

Claims 32 and 34 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,045,818 in view of Nitecki, Kausch and appellants' admitted prior art at page 12, lines 1-12 of the specification.

Claims 14-16 and 33 stand rejected under 35 U.S.C. § 103 as being unpatentable over Herweck in view of Merrill.

Claim 17 stands rejected under 35 U.S.C. § 103 as being unpatentable over Herweck in view of Merrill and Mikos.

We affirm the rejection under the judicially created doctrine of obviousness-type double patenting. We reverse the rejections under 35 U.S.C. § 103.

DISCUSSION

Obviousness-type Double Patenting:

One-way or Two-way test of obviousness:

As a preliminary matter, we focus attention on appellants' arguments concerning which "test" should be used to resolve the issue of obviousness-type double patenting on this record. According to appellants (Brief, pages 15-16), the examiner incorrectly applied the "one-way" test rather than the "two-way" test for obviousness-type double patenting. See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998). In support of this assertion, appellants state (Brief, pages 15-16),

[t]his application was filed March 3, 1995.... This case has twice been on appeal, and that is the major reason it has now been pending for nine-years.

Appellants prosecuted a continuation case while this case was on appeal and were able to convince the examiner that substantially narrower claims should be allowed. The Board then remanded this case to the examiner, it was again prosecuted, and appellants are now back before the Board.

Appellants present similar arguments for both obviousness-type double patenting rejections before us on this record. See Brief, pages 17-22.

For clarity, we make the following observations. On September 29, 1997 appellant filed a Notice of Appeal leading to consideration of the subject matter of then pending claims 1-32 by the Board in Appeal No. 1999-0965 ('0965). After appellants filed their Notice of Appeal, appellants filed two continuation applications: (1) 08/947,063, filed October 8, 1997, now United States Patent No. 5,906,828 ('828); and (2) 09/200,493, filed November 25, 1998, now United States Patent No. 6,045,818 ('818).² Since both applications are direct continuations of the instant application, there is no doubt that the subject matter of both of these continuation applications, now the '818 patent and the '828 patent, could have been presented in the instant application. See Answer, page 14.

Nevertheless, after the briefing stage, an oral hearing for the '0965 appeal was held May 22, 2001. Subsequently, a Decision was entered into the record on July 27, 2001 affirming the rejection of claims 1-13 and 18-31, and reversing the rejection of claim 32. The rejection of then pending claims 14-17 was vacated and the application was remanded to the examiner to "reevaluate the patentability of those claims on prior art grounds and on the ground of obviousness-type double patenting." Decision, bridging paragraph, pages 21-22. Stated differently by the examiner (Answer, page 14), the rejection of 27 of the then pending 32 claims was affirmed.

² As discussed below, both of these patents have been applied in the obviousness-type double patenting rejections on this record.

On reflection, since the subject matter of both the '181 patent and the '182 patent could have been filed in one application appellants are not entitled to receive the benefit of a two-way test of obviousness-type double patenting. See Berg, at 1434, 46 USPQ2d at 1231, "[w]e hold ... if an applicant can file all of its claims in one application, but elects not to, it is not entitled to the exception of the two-way test." Accordingly, we agree with the examiner (Answer, page 14), "[b]ecause the first condition for two-way obviousness[-type double patenting] has not been met, it is not necessary to consider the second condition, i.e. who actually controlled the respective rates of prosecution." See Berg, at 1435, 46 USPQ2d at 1232, "The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application."

For the foregoing reasons, we are not persuaded by appellants' assertion that the examiner incorrectly applied the "one-way" test for determining obviousness-type double patenting on this record. As set forth in Berg, at 1432, 46 USPQ2d at 1229 citations omitted,

Under the one-way test, if the scope of the application and the patent claims is not identical, the court must ask whether the former defines merely an obvious variation of the latter. ... If the application claim is not patentably distinct, in order to overcome the double patenting rejection, the applicant must file a "terminal disclaimer," foregoing that portion of the term of the second patent that extends beyond the term of the first.

In our opinion the examiner was correct in applying the “one-way” test in evaluating the claims under the judicially created doctrine of obviousness-type double patenting.

Claims 14-17 and 33:

According to appellants (Brief, page 5), claims 14-17 and 33 stand or fall together. Accordingly, we limit our discussion to representative independent claim 33. Claims 14-17 will stand or fall together with claim 33. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Answer, page 3), claim 1 of the ‘828 patent differs from claim 33 on appeal, by not requiring the use of “the same attachment agent to link the tether to the substrate and the growth effector molecule.” To make up for this deficiency, the examiner finds (id.), Nitecki and Kausch “disclose that homobifunctional coupling agents and linkers are known for purposes of coupling ... biological materials and for immobilization....”

Accordingly, the examiner concludes (Answer, bridging sentence, pages 3-4), “[i]t would have been [prima facie] obvious to one of ordinary skill in the art [at the time the invention was made] to use the same attachment agent to link the tether to the substrate and the growth effector molecule in the claimed invention of the ‘828 patent ... because the claims of the ‘828 patent require covalent attachment yet are not limited to any particular attachment agents....” In this regard, the examiner notes (Answer, page 4), Nitecki and Kausch disclose that

“homobifunctional coupling agents and linkers are known and useful in the art for the same purpose claimed in the ‘828 patent.”³

In addressing the rejection under the “one-way” test, appellants assert (Reply Brief, page 6), “[t]here are two major differences between the claims [on appeal] which are not obvious from the other claims [(as set forth in the ‘828 patent)].” We will address each “difference” separately. Regarding the first difference, appellants assert (id.), “[t]he Cima ‘828 claims are drawn to a substrate that is implanted into a patient,” whereas the “claims on appeal are drawn to a biocompatible substrate, with no reference to implantation.” In this regard, we note that claim 15 on appeal depends ultimately from claim 33. Claim 15 further defines the composition set forth in claim 33 as “administered by injection, infusion, or implantation.” Accordingly, for claim 15 to properly depend from claim 33, the scope of claim 33 must be open to include a substrate that can be, inter alia, implanted into a patient. Accordingly, we are not persuaded by appellants’ first asserted difference.

Regarding the second difference, appellants assert (Reply Brief, page 6), “[t]he Cima ‘828 claims are drawn to a substrate comprising branched, water soluble tethers having multiple growth factor molecules attached thereto,” whereas the “claims on appeal are drawn to a substrate having a defined density of growth factors attached to one end of polymeric tethers and to the substrate at

³ The examiner relies on page 12, lines 1-12 of appellants’ specification, as an admission “that cyanogens bromide, succinimide, aldehydes, tosyl chloride, avidin-biotin, epoxide, and maleimides are standard immobilization chemistries which are well known in the art.” Answer, page 4. Since appellants do not address this aspect of the rejection we find the examiner’s characterization of the specification to be correct.

the other end.” For clarity, we reproduce the relevant portions of each claim below, the differences between the claims is highlighted:

Claim 33 on appeal:

A method ...

wherein one end of each tether is covalently linked to the substrate and one end is covalently linked to a growth effector molecule so that the growth effector molecule cannot be internalized by cells attached to the substrate;

wherein the growth effector molecules are attached to the substrate in a concentration effective to enhance the rate of target cell growth over the rate of target cell growth with soluble growth effector

Claim 1 of the '828 patent:

A method ...

wherein one end of each tether is covalently linked to the substrate, each tether is able to covalently link more than one growth effector molecule, each growth effector molecule is covalently linked to a distal end of a tether so that the growth effector molecule cannot be internalized by cells attached to the substrate, and

the growth effector molecules are attached to the substrate in a concentration effective to enhance molecules and growth effector molecules adsorbed to a substrate, without internalization of the molecule; and

wherein the tether is covalently linked to the substrate and to the growth effector molecule by the same attachment agents....

the rate of target cell growth over the rate of target cell growth with soluble growth effector molecules and growth effector molecules adsorbed to a substrate, without internalization of the molecules....

According to appellants (Reply Brief, page 6),

[t]he examiner has cited no art that would lead one skilled in the art to substitute the branched tethers of the '828 claims for the tethers of the '799 application so that one would look only at the final concentration of growth factors, not the final density of tethers bound to substrate[.]

Regarding appellants assertions (see Reply Brief, pages 6-9), regarding tether “density” and growth factor “concentration,” we note that both the claims before us on appeal and claim 1 of the ‘828 patent require that the growth effector molecules be present in a “concentration effective to enhance the rate of target cell growth over the rate of target cell growth with soluble growth effector molecules ... without internalization of the molecules.” Accordingly, we are not persuaded by appellants’ focus on tether “density” and growth factor “concentration” as a point of distinction between the two sets of claims.

Therefore, as we understand it, the issue before us is whether it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify claim 1 of the ‘828 patent to use a homobifunctional “tether” that covalently links one growth effector molecule, rather than a “tether” that is able to covalently link more than one growth effector molecule. According to the examiner (Answer, page 3), Nitecki and Kausch “disclose that homobifunctional coupling agents and linkers are known for purposes of coupling ... biological materials and for immobilization....”⁴

Accordingly, the examiner concludes (Answer, bridging sentence, pages 3-4),

[i]t would have been [prima facie] obvious to one of ordinary skill in the art [at the time the invention was made] to use the same attachment agent to link the tether to the substrate and the growth effector molecule in the claimed invention of the ‘828 patent ... because Nitecki et al[.] and Kausch et al[.] teach that the use of homobifunctional coupling agents and linkers are known and useful in the art for the same purpose claimed in the ‘828 patent.

⁴ Appellants agree with this characterization of Nitecki and Kausch. See Reply Brief, page 9 wherein appellants state “Nitecki and Kausch teach linkers for coupling biological agents....”

In response, appellants argue (Reply Brief, page 9), neither Nitecki nor Kausch “suggests that the respective inventions would be useful for growing cells on a biocompatible solid substrate.” We are not persuaded by appellants’ argument. As the examiner points out (Answer, page 3), Nitecki and Kausch “disclose that homobifunctional coupling agents and linkers are known for purposes of coupling ... biological materials and for immobilization....” As set forth in claims 1-4 of the ‘828 patent, linkers are useful for growing cells on a biocompatible solid substrate. Accordingly, contrary to appellants’ assertion, it is our opinion that it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to substitute the homobifunctional linkers taught by Nitecki and Kausch for the branched linkers set forth in the method of claims 1-4 of the ‘828 patent.

For the foregoing reasons we affirm the rejection of claim 33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,906,828 in view of Nitecki, Kausch and appellants admitted prior art at page 12, lines 1-12 of the specification. As discussed supra claims 14-17 fall together with claim 33.

Claims 32 and 34:

According to appellants (Brief, page 5), claims 32 and 34 stand or fall together. Accordingly, we limit our discussion to representative independent claim 34. Claim 32 will stand or fall together with claim 34. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Answer, page 5), claim 20 of the '818 patent differs from claim 34 on appeal by not requiring the use of "the same attachment agent to link the tether to the substrate and the growth effector molecule." To make up for this deficiency, the examiner finds (id.), Nitecki and Kausch "disclose that homobifunctional coupling agents and linkers are known for purposes of coupling ... biological materials and for immobilization...." Accordingly, the examiner concludes (id.), "[i]t would have been [prima facie] obvious to one of ordinary skill in the art [at the time the invention was made] to use the same attachment agent to link the tether to the substrate and the growth effector molecule in the claimed invention of the '818 patent ... because the claims of the '828 [sic] patent require covalent attachment yet are not limited to any particular attachment agents...." In this regard, the examiner notes (id.), Nitecki and Kausch disclose that "homobifunctional coupling agents and linkers are known and useful in the art for the same purpose claimed in the '828 [sic] patent."

Appellants' arguments (Brief, pages 19-22, and Reply Brief, pages 1214), are substantially the same as their arguments with regard to the obviousness-type double patenting rejection of claims 14-17 and 33. Rather than reiterate the deficiency in appellants' argument, we direct attention to the rationale set forth above. Accordingly, for the reasons set forth above, we affirm the rejection of claim 34 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of U.S. Patent No. 6,045,818 in view of Nitecki, Kausch and appellants admitted prior art at page

12, lines 1-12 of the specification. As discussed supra claim 32 falls together with claim 34.

Obviousness:

Claims 14-16 and 33:

Claims 14-16 and 33 stand rejected under 35 U.S.C. § 103 as unpatentable over the combination of Herweck and Merrill. According to the examiner (Answer, page 6), Herweck “disclose a device which can be used for stimulating the growth of eukaryotic blood cells ... and using this device as a ‘matrix and support upon which cellular matter is grown’....” In this regard, the examiner finds (id.), Herweck’s “device consists of a substrate which can be manufactured from any suitable biocompatible material including fibers and polymers...”; it can be implanted and it is “useful for treating a patient in need of cell growth.” In addition, the examiner finds (id.), Herweck “disclose coating the substrate of the device with [a] bioactive material such as platelet derived growth factor, epidermal growth factor, transforming growth factor, erythropoietin, and fibroblast growth factor....” According to the examiner (Answer, bridging paragraph, pages 6-7), “Herweck “achieve an enhanced rate of target cell growth, i.e. growth of cells at the implantation site is enhanced compared to if no implantation had been made, and certain factors which can be present stimulate, i.e. enhance, endothelial cell growth....”

The examiner recognizes, however, that Herweck “do not disclose biocompatible tethers which have one end covalently linked to the substrate and a growth effector molecule covalently linked to the other end.” The examiner

relies on Merrill to make up for this deficiency in Herweck. According to the examiner (Answer, page 7), "Merrill discloses star molecules composed of biocompatible, non-thrombogenic, water-soluble polyethylene oxide (PEO) ... which can have one arm covalently linked to a substrate thereby anchoring the molecule ... and another arm covalently linked to a bioactive molecule...."

Based on this evidence the examiner concludes (Answer, page 7),

[i]t would have been [prima facie] obvious to one of ordinary skill in the art at the time applicants' invention was made to make a composition for use in stimulating the growth of eukaryotic blood cells consisting of a biocompatible substrate, biocompatible tethers and growth effector molecules as described by Herweck et al. using the polyethylene oxide star molecules for the biocompatible tether components as described by Merrill because the star molecules will prevent thrombogenesis from occurring when the device of Herweck et al. is implanted while still ensuring that the device remains coated with the bioactive material.

In response appellants note (Brief, bridging sentence, pages 11-12),

"Herweck does not disclose or suggest the use of a tether attaching a growth effector molecule to a substrate but merely coats, or adsorbs, the factor upon the substrate." Further, appellants assert (Brief, page 12), "Herweck does not describe or provide motivation to lead one of ordinary skill in the art to grow cells by maintaining the cells in contact with the composition defined therein, which comprises a tether attaching a growth effector molecule to a substrate without causing internalization of the effector molecule by the cells." In this regard, appellants assert (id.), "Herweck does not teach that the rate of target cell growth would be enhanced by using tethered growth effector molecules as

compared to simply coating or adsorbing the growth effector molecules to the substrate.”

As we understand it, Herweck’s “invention pertains to an implantable prosthetic device for sustained release of a bioactive material into a fluid flow pathway of a patient.” Herweck, column 3, lines 14-16. Herweck discloses that cells can be grown on the “device”. See e.g., Herweck, column 3, lines 28-34; and column 11, lines 24-49. However, the examiner does not identify, and we do not find, a disclosure in Herweck suggesting that tethering growth factors to such a device would allow for an enhanced rate of target cell growth over the rate of target cell growth with soluble growth effector molecules, as required by appellants’ claimed invention.⁵ In this regard, we note that while Herweck discusses the use of growth factors, the growth factors are “inoculated into various lumina” of the device (Herweck, column 12, lines 1-5), where they can then diffuse “through the walls and into the adjacent lumina which contain body fluid, such as blood.” See e.g., Herweck, column 3, lines 46-49.

Merrill’s invention “pertains to a method for covalently immobilizing polyethylene oxide star molecules onto a support surface and to hydrogels produced by the method.... As such, the immobilized PEO star molecules can

⁵ We recognize the examiner’s statement (Answer, page 11), Herweck “teach an enhanced rate of target cell growth, i.e. growth of cells at the implantation site is enhanced compared to if no implantation had been made....” The examiner’s comment, however, fails to appreciate that the claimed invention requires an enhanced “rate of target cell growth over the rate of target cell growth with soluble growth effector molecules and growth effector molecules adsorbed to a substrate....” See e.g., appellants’ claim 33. Herweck, does not disclose the use of growth effector molecules that are tethered to the device, accordingly, contrary to the examiner’s intimation, Herweck does not teach an enhanced rate of target cell growth over the rate of target cell growth with soluble effector molecules or effector molecules adsorbed to a substrate.

be used as a tool for separating and purifying biological molecules, while greatly reducing or eliminating non-specific binding.” Merrill, column 2, lines 5-13. As we understand it, Merrill’s star molecule hydrogels can be covalently attached to an appropriate support surface and the remaining unattached arms of the star molecule⁶ can be attached to a biopolymer or affinity ligand. See, Merrill, column 4, lines 54-61. In addition, Merrill discloses that “[a]dditional chemical components can be incorporated into the star hydrogels depending upon the application.” Merrill, column 6, lines 18-19. We note, however, that similar to the Herweck’s inoculation of growth factors into the lumina of his device, Merrill discloses that these incorporated components elute from the hydrogel “into the blood flow over a significant period of time.” Merrill, column 6, lines 26-27. The examiner has not identified, and we do not find, a disclosure in Merrill suggesting that tethering growth factors to such a device would allow for an enhanced rate of target cell growth over the rate of target cell growth with soluble growth effector molecules, as required by appellants’ claimed invention.

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. ... Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious

⁶ We note that Merrill discloses that the “arms” of the star molecule that are not attached to a support are available “as molecular leashes or tethers” to which a biopolymer or affinity ligand can be attached. Merrill, column 4, lines 64-65.

effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.”

...
Most if not all inventions arise from a combination of old elements. ... Thus, every element of a claimed invention may often be found in the prior art. ... However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. ... Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [Citations omitted].

In other words, “there still must be evidence that ‘a skilled artisan, ... with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.’” Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). At best, the statement of the rejection establishes that individual parts of the claimed invention were known in the prior art. What is missing, however, is some suggestion to combine these elements in a manner that would have arrived at appellants’ claimed invention.

Furthermore, to establish a prima facie case of obviousness, there must be both some suggestion or motivation to modify the references or combine reference teachings and a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). As discussed above, we find no suggestion to combine the teachings of the references to arrive at appellants’ claimed invention. In addition, however, assuming arguendo, that a person of ordinary skill in the art would have been motivated to combine Herweck and Merrill, the examiner has failed to provide a factual basis to

support a finding that a person of ordinary skill in the art would have had a reasonable expectation of success in obtaining an enhanced rate of target cell growth over the rate of target cell growth with soluble growth effector molecules and growth effector molecules adsorbed to a substrate, without internalization of the molecules, as required by appellants' claimed invention.

On reflection, it is our opinion that the examiner failed to meet his burden⁷ of provided the evidence necessary to support a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Accordingly, we reverse the rejection of claims 14-16 and 33 under 35 U.S.C. § 103 as being unpatentable over Herweck in view of Merrill.

Claim 17:

Claim 17 stands rejected under 35 U.S.C. § 103 as being unpatentable over Herweck in view of Merrill and Mikos. The examiner relies on Herweck and Merrill as applied to claims 14-16 and 33. See supra. According to the examiner (Answer, page 8), "[n]either Herweck et al. nor Merrill disclose a substrate which is biodegradable." The examiner relies on Mikos to make up for this deficiency in Herweck and Merrill. According to the examiner (id.), "Mikos discloses a 'biodegradable, bioresorbable[], three-dimensional template for repair and replacement of diseased or injured bone which provides mechanical strength to bone while also providing a guide for growth of bone tissue'....."

Based on this evidence the examiner concludes (id.),

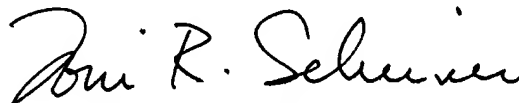
[i]t would have been obvious to one of ordinary skill in the art at the time applicants' invention was made to make a cell growth composition outlined in the above rejection using a biodegradable material as described by Mikos because a patient in need of an implantable cell growth composition might only need it for a defined period of time and it would be less deleterious to the patient and more conducive to overall healing to have the cell growth composition biodegrade and be bioabsorbed so that further surgery and trauma to the patient would not be necessary.

In response, appellants assert (Brief, page 14), "Mikos does not add the elements missing from the Herweck/Merrill combination." We agree.

Accordingly, we reverse the rejection of claim 17 under 35 U.S.C. § 103 as being unpatentable over Herweck in view of Merrill and Mikos.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



Toni R. Scheiner
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge

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⁷ In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

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